Compiled Redline
CIRM Grants Administration Policy
for Academic and Non-Profit Institutions

Key:

Original Document- footer OAL Approved – Eff. 3/30/07

Changes to the Original Document that were proposed in initial OAL filing are marked as follows:
Deletions are marked with a single strikethrough- ~~strikethrough~~
Additions are marked with a single underline- underline
The proposed changes in the initial OAL filing are contained in document with footer, "Proposed amendments July 15, 2008".

Changes from the Original Document and from the amendments that were proposed in the initial OAL filing of amendments are highlighted in yellow and marked as follows:
Deletions are marked with a double strikethrough- ~~double strikethrough~~
Additions are marked with a double underline- double underline
The further amendments, which are subject to the 15-day process, are contained in this document with footer, "Combined Redline November 10, 2008".

I. GENERAL INFORMATION

C. Defined Terms ~~Glossary~~

Award	CIRM funding in the form of a ~~grant~~Grant, loan or contract that is~~The provision of funds by CIRM~~, based on an approved ~~application~~Application and budget or ~~progress report~~Progress and Financial Reports~~, to an organizational entity or an individual to carry out a project or activity.~~
Budget P~~p~~eriod	The intervals of time (usually 12 months ~~each~~) into which a P~~p~~roject P~~p~~eriod is divided for budgetary, ~~and~~ funding and reporting purposes.

Indirect Ceosts	Administrative costs of ~~an~~ a Granteeorganization incurred for common or joint objectives, which cannot be readily and specifically identified with a particular grantGrant project. Indirect costs may not exceed ~~will be limited to~~ a maximum of 25 percent of Ddirect Rresearch Ffunding Ceosts exclusive of the costs of equipmentEquipment, tuition and feesTuition and Fees, and Ceonsultant fees or Ssubcontract amounts in excess of $25,000.

E. Roles and Responsibilities

1. CIRM Staff:
c. Scientific Program Officer (SPO)

c. Scientific Program Officer (SPO)
The SPO is responsible for the programmatic, scientific, and technical aspects of ~~application~~ Applications and Awards ~~grants~~. The SPO's responsibilities include, but are not limited to, developing research and research training programs to support the CIRM mission; providing consultation and assistance to applicants and PIs ~~grantee~~ in scientific and programmatic areas, including guidance on CIRM ~~grants~~ policies and procedures, and performing post-award administration such as reviewing ~~progress report~~ Progress Reports, coordinating site visits and closing out ~~g~~Grants. The SPO works with the SRO in pre-award administration, and with the GMO in post-award activities. The name of the assigned SPO and his/her contact information is provided with the NGA.

II. GRANT APPLICATION AND REVIEW PROCESS

D. Application Review

~~2.~~**2.** ***Provisionally Recommended for Funding*** (Tier 2) – For meritorious grant and loan A~~a~~pplications that require further consideration by the ICOC. The GWG may change the designation as needed to reflect the appropriate communication to the ICOC regarding the merit of the A~~a~~pplications in Tier 2.~~are recommended to the ICOC for funding pending available funds.~~

F. Appeals of Scientific Review

~~The a~~A~~r~~The applicant~~s~~ should carefully examine the review report provided by CIRM. Any questions about the conduct of the review must first be raised with the SRO responsible for the review meeting in question. If an applicant's concern cannot be informally resolved in

consultation with the SRO, CIRM will accept a request for a formal appeal.

Grounds for ~~An applicant may then lodge~~ a formal appeal ~~of the review~~ are strictly limited to circumstances in which ~~only if the applicant can show that~~ an applicant can show that a demonstrable financial, professional or personal ~~or scientific~~ conflict of interest had a negative impact on the review process and resulted in a flawed review. ~~This shall be the only ground for appeal.~~ This shall be the only ground for appeal. Differences of scientific opinion between or among PIs and reviewers are not grounds for appeal.

To lodge an appeal, the applicant must submit a written ~~an appeal~~ request ~~in writing~~ to the SRO or to the ~~Director of Scientific Activities~~Chief Scientific Officer~~The deadline for submission is~~ within 30 days from the date that ~~of~~ CIRM~~'s making~~ makes the review report available to the applicant. CIRM staff will then assess the merits of the appeal in consultation with the Chair and Vice-Chair(s) of the GWG ~~will then assess the merit of the appeal~~ ~~request in consultation with the chair of the SMRFWG~~ and present a written recommendation to the President of CIRM. If the ~~e~~Chair of the ~~SMRF~~GWG has a financial, professional or personal ~~or scientific~~ conflict of interest (as defined in Cal. Code Regs., Title 17, section 100003) in the ~~with the a~~Application that is the subject of the appeal, staff will consult with an eligible ~~as determined by ICOC policy adopted pursuant to Health and Safety Code section 125290.50(e), a different~~ scientific member of the ~~SMRF~~GWG (i.e., a member who has no financial, professional or personal ~~or scientific~~ conflict of interest). ~~will be consulted.~~ If the Vice-Chair(s) of the GWG has a conflict of interest in the Application (as defined in Health & Safety Code section 125290.30(g)), staff will consult with an eligible patient advocate member of the GWG (i.e., a member who has no conflict of interest). The President of CIRM will consider the appeal and the recommendations and issue a ~~then make the~~ final written decision on the merits of the appeal.

~~If the President determines that an appeal is meritorious, then the a~~Application ~~will be reevaluated for scientific merit by two scientist members of~~ ~~receive a new review by~~ ~~the SMRFGWG.~~ If an appeal is meritorious, the Application will receive a new review by the following members of the GWG: (1) the Chair of the GWG; (2) the Vice-Chair(s) of the GWG; (3) at least two, but no more than three, scientific reviewers of the GWG or specialists selected by CIRM staff in consultation with the chair of the GWG; and (4) if the Application is for disease-specific research, the patient advocate member of the GWG who was appointed from an advocacy group for that disease, provided that he or she is eligible to participate.

If any of the members in categories (1) through (3) above has a conflict of interest in the Application under the applicable conflict of interest policies, staff shall select an eligible scientific or patient advocate member, as appropriate, to serve in his or her place. Members in categories (2) and (4) above may waive their participation, or if they do not have a conflict of interest in the Application, designate another eligible patient advocate member of the GWG to participate in their place.

CIRM staff, in consultation with the members in categories (1) through (4) above, will set a date for the review. At least two weeks before the scheduled review, all eligible patient advocate members of the GWG will be invited to participate. The Application will be reviewed pursuant to the procedures for the review of Applications set forth in the GWG bylaws, provided, however, that the quorum requirements shall not apply. A summary of the ~~The resulting~~ new review and recommendation ~~A recommendation based on the new review~~ will ~~then~~ be ~~presented~~ submitted to the ICOC, which will make the final decision on funding the ~~a~~Application in question.

III. PRE-AWARD AND AWARD

~~C.~~C. Public Policy Requirements

~~2.~~2. Conflict of Interest

Grantees must establish safeguards to prevent employees, C~~c~~onsultants, contractors, collaborators, and members of governing bodies who may be involved in CIRM~~grant~~-funded~~supported~~ A~~a~~ctivities from participating in or in any way attempting to use their position to influence those activities in which they know or have reason to know they have a financial interest. Grantees must enforce within their institutions all such applicable safeguards. If the G~~g~~rantee uses contractors or collaborators to conduct~~carries out~~ CIRM-funded research ~~through contractors or collaborators~~, the G~~g~~rantee ~~institution~~ must take reasonable steps to ensure that such contractors or collaborators~~investigators working for such entities~~ comply with ~~established~~ the Grantee's safeguards. An acceptable standard for such a policy, for example, may be found in 42 CFR Part 50, Subpart F (*Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought*) (effective October 1, 2000). The G~~g~~rantee ~~organization~~ must promptly notify CIRM if and when it~~the grantee organization~~ takes a suspension or separation action involving a financial conflict of interest against a PI or other Recipient of CIRM funding~~investigator on the CIRM grant~~.

9. Sharing of Intellectual Property: Publications, Biomedical Materials, Patented Inventions

PIs and ~~CIRM grantee~~ Grantees shall share intellectual property generated by CIRM-funded research ~~under a CIRM grant~~ including research results in scientific articles, publication-related biomedical materials, and patented inventions for research use in California as required by ~~Title 17, California Code of Regulations section 100300, et seq. and section 100400, et seq., as applicable.~~ ~~CIRM regulations duly adopted by the ICOC~~. CIRM regulations duly adopted by the ICOC.

10. Preference for California Suppliers

It is a goal of Proposition 71 that more than 50 percent of the goods and services used in CIRM-supported research is purchased from California suppliers (Health and Safety Code section 125290.30, subpart (i); Title 17, California Code of Regulations section 100502). To achieve this goal, CIRM expects the Ggrantee to purchase from California suppliers, to the extent reasonably possible, the goods and services it uses in its CIRM-supported research. The PI and Ggrantee must provide a clear and compelling explanation in the ~~its annual~~ ~~pProgrammatic~~ Progress ~~r~~Report for not purchasing more than 50 percent of its goods and services from California suppliers. Please see chapter V, section H, part 2, ~~*Programmatic*~~ *Progress Report*.

~~[A definition for the term "California Supplier" is being separately considered as an interim regulation and will be added to this document for additional notice and comment consistent with that interim regulation.]~~

V. PAYMENT AND USE OF FUNDS

A. Payment

Once CIRM has a fully-executed NGA, it will ~~The~~ initiate~~l~~ payment for the first Budget Period ~~an approved application is made after award acceptance~~. Payment for each subsequent ~~future budget period~~ Budget Period is contingent on the receipt and acceptance by CIRM of the financial, progress~~programmatic~~, and other reports due for the prior ~~budget period~~ Budget Period; applicable public policy assurance documents (e.g., ~~E~~SCRO, IRB, and IACUC); and any requests for budget changes applicable to the new ~~budget period~~ Budget Period.

B. Costs and Activities

1. Allowable Project Costs and Activities

Project costs are those costs that can be specifically identified with a CIRM-funded ~~particular project~~ Project or ~~a~~Activity ~~under a CIRM grant~~. Unless otherwise specified in an RFA or NGA, allowable project costs include salary for investigators (detailed below), fringe benefits, itemized supplies, S~~s~~tipends and ~~tuition and fees~~Tuition and Fees (as defined in chapter VI, section C, *Allowable Costs and Activities for Training Grants*), research animal costs, C~~c~~onsultants, itemized clinical study costs, travel-related expenses (detailed below), itemized project-related ~~equipment~~Equipment (as approved), publication costs, service contracts, Subcontracts, and administrative costs where required to carry out the approved

project. For specific allowable costs related to training grants see chapter VI, section C, *Allowable Costs and Activities for Training Grants*~~)~~.

Subcontracts or consulting agreements with individuals or organizations located outside the State of California must be justified and are limited to $15,000 per Budget Period and $25,000 per Budget Period in aggregate, unless Prior Approval is sought and obtained during administrative review.

~~Investigator s~~Salaries for PIs, PDs and Key Personnel shall not exceed~~be limited to~~ an annual rate of $20700,000 ~~per investigator~~. CIRM will adjust this ~~This~~ limitation ~~shall be adjusted~~ biennially ~~by CIRM~~ beginning July~~anuary~~ ~~2~~1, 20~~0~~10~~8~~ as follows: (a) the base dollar amount of $20~~7~~0,000 shall be increased or decreased by the cumulative percentage change in the annual average California Consumer Price Index for All Urban Consumers from 200~~8~~6 to the end of the calendar year immediately preceding the year in which the adjustment will take effect and (b) the dollar amount obtained by ~~application~~A~~a~~pplication of the calculation set forth in subdivision (a) shall be rounded to the nearest $1,000. The resulting figure shall be the adjusted maximum annual salary ~~rate limitation~~ in effect until June~~anuary~~ ~~1~~30of the next even-numbered year. Biennial adjustments will be posted at www.cirm.ca.gov.

3. Allowable Facilities Costs

Facilities costs cover general operating costs of the G~~g~~rantee's facilities attributable to housing ~~that will house~~ all elements of the CIRM-funded ~~project~~ Project or ~~activity~~Activity. Grantees may request two categories of facilities costs: (a) costs based on the G~~g~~rantee's current, federally negotiated rates for O~~o~~peration and M~~m~~aintenance E~~e~~xpenses, and for ~~library expense~~Library E~~e~~xpenses; and (b)(1) costs based on the grantee's current, federally negotiated rates for depreciation or use allowances on buildings, capital improvements, and ~~equipment~~Equipment, and for interest on capital debt, as a proxy for a market lease rate of reimbursement (Health and Safety Code section 125292.10, subdivision (u)); or (b)(2) the actual out-of-pocket lease cost incurred by a ~~grantee~~Grantee if the ~~grantee~~Grantee leases space to conduct approved research; this cost must be reported in the Annual Financial Report (see chapter V, section H, part 1, *Annual Financial Report*). ~~Grantee~~Grantees may request both categories (a) and (b) as allowable facilities costs. Rates from both categories shall be applied to the total allowable project costs exclusive of costs of ~~equipment~~Equipment, ~~tuition and fees~~Tuition and Fees, and S~~s~~ubcontract amounts in excess of $25,000.

5. Indirect Costs

~~Indirect cost~~Indirect Costs will be limited to a maximum of 25 percent of allowable ~~direct research funding costs~~Direct Research Funding Costs ~~awarded by CIRM (i.e., project costs and facilities costs)~~, exclusive of the costs of ~~equipment~~Equipment,

~~tuition and fees~~Tuition and Fees, and S~~s~~ubcontracts or C~~c~~onsultant fees~~amounts~~ in excess of $25,000.

6. Interest Earned on CIRM Funds

Interest earned on CIRM funds must be reinvested in the program that the funds support. Carry forward reported on a financial report must include any interest earned during the expired B~~b~~udget P~~p~~eriod. Interest on CIRM funds may be determined according to the Grantee's own interest cycle but, at a minimum, must be calculated at a monthly rate. Grantees are required to include a copy of the interest calculations in their financial report.

C. Budgetary Overlap

Pre-award Costs: After the ICOC approves an Application for funding, a ~~A~~Grantee may, at its own risk and without Prior Approval, incur obligations and expenditures to cover costs up to 90 days prior to the effective date of Award if such costs are necessary to conduct the project and would be allowable if the Application were funded. If specific expenditures or activities would otherwise require Prior Approval, the Grantee must obtain CIRM approval before incurring the cost. A Grantee's decision to incur pre-award costs in anticipation of an Award imposes no obligation on CIRM either to make the Award or to increase the amount of the Approved Budget if an Award is made for less than the amount anticipated and is inadequate to cover pre-award costs incurred. Grantees are on notice that a decision to incur pre-award costs is a decision to borrow against future support and that such borrowing must not impair the Grantee's ability to accomplish the project objectives in the approved time frame or in any way adversely affect the conduct of the CIRM-funded Project.

D. Prior Approval Requirements

2. Carry Forward of Funds

PIs~~'~~ and ~~The g~~Grantees must obtain ~~prior approval~~ Prior Approval ~~from CIRM~~ to carry forward from one Budget Period to the next unexpended funds exceeding 25 percent of the annual ~~project~~ budget ~~costs~~ for the expiring Budget Period ~~from one budget period to the next that exceed 25 percent of the annual project costs for the expiring budget period.~~ Absent Prior Approval, any amount that exceeds this limit will be deducted from the payment of funds for the next ~~budget period~~ Budget Period ~~unless approval to carry the amount forward is granted.~~ If the carry forward amount is greater than 50 percent of the expiring ~~budget period~~ Budget Period's project costs, CIRM may elect to postpone payment of funds for the next ~~budget period~~ Budget Period ~~may be postponed. At the conclusion or termination of an award.~~ U~~u~~nexpended funds must be returned to CIRM within 120 days of the ~~project period~~ Project Period end date.

3. Extensions

PIs~~/~~ and Grantees may request a one-time, no-cost extension of the Project Period end date of~~or~~ up to one year ~~beyond the scheduled project period end date~~. A request and justification for a no-cost extension must be submitted to the GMO in writing at least 30 days prior to the original ~~award project period~~ Project Period end date.

5. Relinquishment of Award and Award Transfer
~~5. Award Transfer~~

A Grantee may at any time relinquish an Award by submitting a relinquishing statement that includes a) a statement of reasons for relinquishing the ~~reward~~Award; b) an estimate of the unexpended balance of any funds paid to the Grantee; c) and an assurance that all unexpended funds will either be returned to CIRM, or in the case of an Award transfer, transferred to a new Grantee within 90 days of the date of relinquishment. In the case of a transfer, the relinquishing Grantee may be required to transfer CIRM-funded equipment purchased with the Award.

H. Reporting Requirements

2. ~~Annual~~ Progress~~mmatic~~ Report

The G~~g~~rantee shall submit to CIRM an annual ~~programmatic report~~Progress Report detailing scientific progress and activities, unless CIRM requires more frequent reports ~~under the CIRM grant~~. This report is due 60 days prior to each anniversary of the A~~a~~ward start date stated~~indicated~~ in the NGA.

The ~~programmatic report~~Progress Report shall include~~s~~ a summary of scientific progress; a listing of personnel who participated in the project and their level of effort; an updated list~~ing~~ of O~~o~~ther S~~s~~upport for the PI ~~and other key personnel~~; a list of publications ~~(including submitted or in press)~~ resulting from the CIRM-funded~~supported~~ ~~project~~ Project or ~~activity~~Activity; cumulative subject accrual and progress in conducting analyses for sex/gender and race/ethnicity differences in clinical trials; applicable public policy assurances (e.g., ESCRO, IRB, IACUC); a statement of the percentage of~~n estimate of~~ goods and services purchased with CIRM funds from California suppliers; and a listing of inventions disclosed, patents filed, or licenses granted for the ~~project period~~Project Period (see part 3, *Other Reports*). The ~~programmatic report~~Progress Report must also include an overview of any major unexpected expenditure~~s~~ or unspent funds (actual or anticipated) for the expiring ~~budget period~~Budget Period and any ~~anticipated~~ changes anticipated for~~in~~ future ~~budget period~~Budget Period~~s~~.

CIRM will not issue payment for the subsequent Budget Period until it has received, reviewed and approved this report.

3. Other Reports

PIs and Grantees are ~~may~~ also ~~be~~ required to report to CIRM publications, inventions, patent applications, licensing and invention utilization activities that result from CIRM ~~-~~ funded research~~ing~~. Specific reporting requirements related to these areas may be found in regulations adopted by the ICOC governing intellectual property ~~for non-profit organizations~~. ~~See Title 17 California Code of Regulations section 100300 et seq., section 100400 et seq.~~

I. Grant Close-Out

CIRM will close out an Award ~~grant~~ within ~~60~~ 90 days ~~as soon as possible~~ after the ~~project period~~ Project Period end date or the end date of any authorized extension. Close-out requires ~~includes~~ a PI and Grantee to timely submit~~ssion~~ of all required reports and reconciliation~~ng~~ of amounts due the Ggrantee or CIRM. CIRM may withhold funds ~~from a PI~~ for future or concurrent ~~award~~ Awards if a Grantee is delinquent in submitting ~~grant close-out is pending the submission of overdue~~ reports.

J. Failure of Compliance

If a Ggrantee or PI fails to comply with the terms and conditions of an A~~a~~ward, CIRM may take one or more actions, depending on the severity and duration of the non-compliance. F~~or instance, f~~ailure of compliance includes confirmed instances of research misconduct, violations of medical or ethical standards as provided ~~defined~~ in Title 17, California Code of Regulations, ~~commencing with~~ section 100010 et seq., or violations of intellectual property regulations, ~~as provided in Title 17, California Code of Regulations, section 100300 et seq~~. ~~duly adopted by the ICOC~~ duly adopted by the ICOC. CIRM will afford the Ggrantee an opportunity to correct any ~~the~~ deficiency~~ies~~ before taking action unless public health or welfare concerns require immediate action, or prompt action is necessary ~~Even if a grantee is taking corrective action, CIRM may take action~~ to protect CIRM's interests. (See also chapter III, section C, part 1, *Research Conduct*)

VI. SPECIAL POLICIES FOR TRAINING GRANTS

E. Reporting Requirements for Training Grants

Notwithstanding chapter V, section H, *Reporting Requirements*, the PD ~~program director of a CIRM training grant~~ must submit ~~report~~ financial and ~~P~~programmatic Progress Reports ~~progress~~ as described in this section to CIRM on an annual basis. The ~~programmatic report~~ Progress Report is due 60 days prior to each anniversary of the ~~project period~~ Project Period

~~award~~ start date stated ~~indicated~~ in the NGA. Funding for ~~t~~The subsequent ~~budget period~~ Budget Period ~~year's funding~~ will not be paid ~~awarded~~ until CIRM has ~~this report has been~~ received, reviewed, and approved this report ~~by CIRM~~. In addition, the PD ~~program director~~ must submit an annual financial report within 90 days after each anniversary of the ~~project period~~ Project Period ~~award~~ start date.

1. **Annual Financial Report**
   The G~~g~~rantee shall submit to the GMO an annual financial report, within ~~960~~ 90 days after each anniversary of the ~~project period~~ Project Period ~~award~~ start date stated ~~indicated~~ in the NGA. The annual financial report must include all actual costs incurred ~~under the CIRM grant~~ during the expired ~~budget period~~ Budget Period and any carry forward amounts.

2. **Annual ~~Programmatic~~ Progress Report**
   The G~~g~~rantee shall submit ~~to CIRM~~ an annual report detailing progress and activities of the training program during the ~~project period~~ Budget Period. This report is due 60 days prior to each anniversary of the ~~project period~~ Budget Period ~~award~~ start date indicated in the NGA. The ~~programmatic report~~ Progress Report for training grants includes two components: a description of the training program and an account of the appointed trainees.

3. **Appointment**

   a. Trainee Appointment Form
   A Trainee Appointment Form ~~(Rev. 6/2006)~~ must be completed for each trainee and submitted ~~to CIRM~~ at the time of appointment. The form requests information about the appointment such as the name of trainee, name of mentor, anticipated period of training, level of ~~stipend~~ Stipend support, and anticipated program of training ~~(e.g., proposed research project)~~. The mentor ~~(if required)~~, trainee, and PD ~~program director~~ must sign the form and in so doing all parties agree to comply with the proposed training program, period of support, ~~stipend~~ Stipend level, and the terms and conditions specified in this G~~g~~rants A~~a~~dministration P~~p~~olicy ~~statement~~. ~~To amend or update any individual trainee information, Grantees must complete and submit a revised Trainee Appointment form to CIRM~~. The completed and signed form is the official document for establishing the ~~stipend~~ Stipend, which should be reflected in ~~the~~ annual financial reports.

   b. Trainee Termination Form
   A Trainee Termination Form must be completed for each trainee and submitted to CIRM at the time of termination of the trainee appointment due to expiration of the appointment period or early termination prior to the pre-determined appointment period. The form requests information about the appointment term, such as the final term of appointment, a summary of the training received during the appointment

period, the Stipend support received during the appointment period, post-award activities (if known) of the trainee, and trainee contact information after completing CIRM support. The trainee and the PD must sign the form.

4. Other Reports

Grantees are~~may~~ also be required to report to CIRM publications, inventions, patent applications, licensing and invention utilization activities that result from CIRM-funded Activities~~ing~~. Specific reporting requirements ~~related to these areas~~ may be found in regulations adopted by the ICOC governing intellectual property, ~~Title 17 California Code of Regulations, section 100300 et seq., and section 100400 et seq for non-profit organizations~~.

6. Ethical Research Practices

Appointed trainees (and their faculty mentors, where applicable) must conduct research in accordance with the highest medical and ethical standards, including compliance with institutional requirements, and regulations set forth and approved by the ICOC. See Title 17 California Code of Regulations section 100010, et seq.

Trainees may not initiate or engage in research activities without documented institutional approvals where required by CIRM or the Grantee. The Grantee must submit to CIRM, with the Annual Progress Report, documentation that certifies that each appointed trainee has current institutional approval (where appropriate) to conduct research involving 1) the use of live vertebrate animals, 2) use of Covered Stem Cell Lines (as specified in Title 17, California Code of Regulations, section 100070), or 3) use of H~~h~~uman S~~s~~ubjects. Certification must be given by the Grantee's official institutional approval committee. The documentation must include for each trainee, the period for which approval has been granted, the name of the PI, and the approval number or identifier. ~~Upon appointment of a trainee, the program director must submit to CIRM documentation (where appropriate) pertaining to the trainee's research project that:~~

~~a.verifies IACUC review and approval of the project's proposed use of live vertebrate animals; or~~
~~b.certifies SCRO, ESCRO committee (or equivalent) notification or review and approval of the project's proposed use of "covered stem cell lineCovered Stem Cell Lines" as specified in Title 17, California Code of Regulations, section 100070; or~~
~~c.certifies IRB review and approval (including applicable documents outlined in the chapter III, section C, part 6, *Research Involving Human Subjects*) of the project's proposed use of human subjectHuman Subjects.~~